# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

# Joint Meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland November 5, 2015

# **MEETING ROSTER**

# **DESIGNATED FEDERAL OFFICER (Non-Voting)**

# Jennifer Shepherd, RPh

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

# ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

# \*Ellen M. Andrews, PhD

(Consumer Representative)

**Executive Director** 

CT Health Policy Project

New Haven, CT

# Lindsey R. Baden, MD

Director of Clinical Research

Division of Infectious Diseases

Brigham and Women's Hospital

Director, Infectious Disease Service

Dana-Farber Cancer Institute

Associate Professor,

Harvard Medical School

Boston, MA

# Demetre C. Daskalakis, MD, MPH

**Assistant Commissioner** 

Bureau of HIV Prevention and Control

New York Department of Health and Mental

Hygiene

Queens, NY

# Vincent Lo Re, MD, MSCE

Assistant Professor of Medicine and Epidemiology

Division of Infectious Diseases

Department of Medicine

Center for Clinical Epidemiology and Biostatistics

Perelman School of Medicine

University of Pennsylvania

Philadelphia, PA

# Antonio Carlos Arrieta, MD

**Division Chief** 

Division of Infectious Diseases

Children's Hospital of Orange County

Orange, CA

# Amanda H. Corbett, PharmD, BCPS, FCCP

Clinical Associate Professor

University of North Carolina

Eshelman School of Pharmacy and School of

Medicine

Global Pharmacology Coordinator

Institute for Global Health and Infectious Diseases,

University of North Carolina

Chapel Hill, NC

# Jonathan Honegger, MD

Assistant Professor of Pediatrics

The Ohio State University College of Medicine

Division of Infectious Diseases and Center for

Vaccines and Immunity

Nationwide Children's Hospital

Columbus, OH

# **CAPT Monica E. Parise, MD**

(Chairperson)

Chief, Parasitic Diseases Branch

Division of Parasitic Diseases and Malaria

Center for Global Health

Centers for Disease Control and Prevention

Atlanta, GA

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# **MEETING ROSTER (cont.)**

# ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

# Marc H. Scheetz, PharmD, MSc

Associate Professor of Pharmacy Practice Midwestern University Chicago College of Pharmacy Downers Grove, IL

# DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

#### Kelly Besco, PharmD, FISMP, CPPS

Health-System Medication Safety Coordinator Ohio-Health Pharmacy Services Dublin, OH

# Tobias Gerhard, PhD, RPh

Associate Professor Rutgers University Department of Pharmacy Practice and Administration Ernest Mario School of Pharmacy New Brunswick, NJ

# Christopher H. Schmid, PhD

Professor of Biostatistics Center for Evidence Based Medicine Department of Biostatistics Brown University School of Public Health Providence, RI

# Almut Winterstein, RPh, PhD, FISPE

Clinical Professor of Pharmacy Practice University of Georgia College of Pharmacy

Niteesh K. Choudhry, MD, PhD

Brigham and Women¹s Hospital

Clinical Research and Education

Georgia Regents Medical Center

**Delivery Sciences** 

Pharmacy Coordinator

Boston, MA

Augusta, GA

Associate Professor, Harvard Medical School

Marjorie Shaw Phillips, MS, RPh, FASHP

Executive Director, Center for Healthcare

Professor and Interim Chair
Pharmaceutical Outcomes & Policy
College of Pharmacy
Epidemiology, College of Public Health and Health
Professions and College of Medicine
University of Florida
Gainesville, FL

# **TEMPORARY MEMBERS (Voting)**

# James S. Floyd, MD, MS

Assistant Professor of Medicine University of Washington Seattle, WA

#### Beth B. Hogans, MS (Biomath), MD, PhD

Associate Professor
Director of Pain Education
Department of Neurology
Johns Hopkins School of Medicine
Baltimore, MD

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# **MEETING ROSTER (cont.)**

# TEMPORARY MEMBERS (Voting) (cont.)

# I. Jon Russell, MD, PhD, ACR Master

Medical Director

Fibromyalgia Research and Consulting

San Antonio, TX

#### Roland Staud, MD

Professor, Rheumatology and Clinical Immunology

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# Jennifer A. Schwartzott, MS

(Patient Representative)

Ambassador and Chair of the Adult Advisory

Council Team

United Mitochondrial Disease Foundation

North Tonawanda, NY

#### Benedetto Vitiello, MD

Chief, Treatment and Prevention Intervention

Branch

Division of Services and Intervention Research

National Institute of Mental Health National Institutes of Health

Bethesda, MD

# **ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEES (Non-Voting)**

#### Nicholas Kartsonis, MD

(Industry Representative)

Section Head, Antibiotics/Antibacterials/CMV

Associate Vice President, Clinical Research

Infectious Diseases

Merck Research Laboratories

Upper Gwynedd Township, PA

# FDA PARTICIPANTS (Non-Voting)

# Edward M. Cox, MD, MPH

Director

Office of Antimicrobial Products (OAP)

Office of New Drugs (OND), CDER, FDA

# Joseph Toerner, MD, MPH

Deputy Director for Safety

DAIP, OAP, OND, CDER, FDA

# Judy Staffa, PhD, RPh

Director

Division of Epidemiology II

Office of Pharmacovigilance and Epidemiology

(OPE), OSE, CDER, FDA

#### Sumati Nambiar, MD, MPH

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Division of Anti-Infective Products (DAIP)

OAP, OND, CDER, FDA

# Robert Ball, MD, MPH, ScM

**Deputy Director** 

Office of Surveillance and Epidemiology (OSE)

CDER, FDA

# Scott Proestel, MD

Director, Division of Pharmacovigalence II

OPE, OSE, CDER, FDA